

# EXHIBIT L

UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

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|                              |   |                                |
|------------------------------|---|--------------------------------|
| STACEY WOLKING and DARYL     | : |                                |
| WOLKING, W/H                 | : |                                |
|                              | : |                                |
| Plaintiffs,                  | : | Civil Action#3:23-cv-00806-MEM |
|                              | : |                                |
|                              | : |                                |
| vs.                          | : |                                |
|                              | : |                                |
| HENRY LINDNER, M.D., AND     | : |                                |
| YOUNGS APOTECARY, INC. D/B/A | : | JURY TRIAL DEMANDED            |
| TUNKHANNOCK COUMPOUNDING     | : |                                |
| CENTER                       | : |                                |
|                              | : |                                |
| Defendants.                  | : |                                |

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**EXPERT REPORT OF CARL GAINOR, Ph.D., J.D. SUBMITTED ON  
APRIL 24, 2024 ON BEHALF OF PLAINTIFFS**

**Academic and professional credentials**

I attended the University of Michigan for pre-pharmacy studies, and then completed my BS degree in pharmacy at the University of Pittsburgh. After graduation, I completed a residency in hospital pharmacy at the Veterans Administration Hospital facilities in Pittsburgh, PA, and then entered the graduate program at the University of Pittsburgh obtaining M.S. and Ph.D. degrees from the School of Pharmacy. After completion of my Ph.D., I entered the School of Law at the University of Pittsburgh, earning my J.D. degree. While attending graduate school, I gained practical work experience as a staff pharmacist at one of the University of Pittsburgh Medical Center hospitals. I am currently licensed to practice pharmacy in Pennsylvania and North Carolina.

I have been admitted to practice law in the Courts of Pennsylvania, in the U.S. Federal District Court for the Western District of Pennsylvania, and in the U.S. Supreme Court. I served as legal counsel to the Pennsylvania Pharmacists Association for 25 years, and I have presented over 500 lectures throughout the United States and Canada on legal aspects of health care.

My academic work involved concurrently teaching the pharmacy law course at various schools of pharmacy, including the University of Pittsburgh for over 40 years, where the course stressed pharmacy laws and regulations and the legal and professional obligations of pharmacists. Additionally, I taught at West Virginia University for over 15 years, the University of Arizona for over 20 years, Notre Dame of Maryland University for 9 years, and Belmont University for 8 years, and in all the courses I stressed the legal and professional duties of a pharmacist. More specificity on dates may be obtained from my CV which has been previously provided and is incorporated herein.

I have been qualified as an expert witness in several jurisdictions, and have never been disqualified in any jurisdiction.

**List of Cases and Publications:**

During the previous 4 years I have testified as an expert witness at trial or by deposition in the following cases:

United States of America v. Richard A Stehl, Case No. 2:18-CR-358-TFM-SMD on 12/03/2019 (Middle District of Alabama, Northern Division)

United States of America v. Shaffer Pharmacy, Inc., et al., Case No. 3:21 CV 22 on 01/28/2021 (Northern District of Ohio, Western Division)

In the previous 10 years I have contributed to one publication:

*The opioid abuse and misuse epidemic: implications for pharmacists in hospitals and health systems*, Am J Health Syst Pharm, 2014 Sept 15;71(18):1539-54.

**Compensation:** I am being compensated for my work on this case at the rate of \$ 300.00 per hour. The fee is not contingent on the content of this Report or the outcome of this case. `

**Materials reviewed:**

The following materials were reviewed relative to the preparation of this Report:

1. Complaint
2. Deposition transcripts of Courtney Young taken on April 03,2024 and November 15, 2023
3. Deposition transcript of Brian Bryk taken on Feb 02, 2024
4. Deposition transcript of Henry Lindner, M.D. taken on Feb 21, 2024

5. Package insert from Amneal Pharmaceuticals on prednisone
6. Patient prescription history report
7. Patient dispensing report with copy of one prescription

**Expert Opinion:** I offer the following Expert Opinions with a reasonable degree of professional certainty and based upon my over 40 years' experience working in the profession of pharmacy and teaching pharmacy law, including the legal and professional responsibilities of pharmacists, to thousands of pharmacy students. I reserve the right to amend or modify this Report should I be provided with additional documents, information, or facts relative to the issues in this matter.

Tunkhannock Compounding Center ("TCC") is a compounding pharmacy located in the same building in Tunkhannock, Pennsylvania, as the medical office of Dr. Henry Lindner. Dr. Lindner had sent prescriptions to TCC for many years, including before Courtney Young became the sole owner of TCC. Young became the sole owner and pharmacist-in-charge of TCC in 2020, and during the times relevant to this case, she employed one other pharmacist, Brian Bryk.

Dr. Henry Lindner began treating Stacey Wolking, hereinafter, "SW", in or about 2021 for what he diagnosed as babesiosis, although that diagnosis was never confirmed with any clinical tests recognize by the CDC or the general medical community. His treatment plan was likewise not generally accepted by the CDC or the general medical community, especially since it involved prescribing massive doses of corticosteroids. By late 2022, SW was taking between 130 mg and 280 mg of prednisone per day, which was an extreme and quite dangerous dosage level. By late September, 2022 SW reported to her doctor that she was taking between 672 and 775 mg of prednisone, and on September 27, 2022 she reported to her doctor that she had taken 1,610 mg of prednisone in the previous 30 hours. On October 4, 2022 her husband reported that SW had consumed 1,848 mg of prednisone. These extreme dangerous doses continued into early October, 2022, with the doctor substituting an even more potent corticosteroid, dexamethasone, for the prednisone. Shortly thereafter SW was hospitalized with a small bowel perforation, admitted to hospice for a period of time, and ultimately discharged to a rehabilitation hospital where she remained until November 17, 2022.

In August of 2022 Dr. Lindner wrote to SW instructing her to have her

corticosteroid prescriptions filled at Tunkhannock Compounding Center, (TCC), as her local pharmacy might report the doctor to his medical board. In early August, 2022 TCC provided SW with 2,120 prednisone 5 mg tablets, which would be approximately 10,600 mg of prednisone. Eight days later TCC filled a second prescription for 200 dexamethasone 4 mg tablets. Dexamethasone is between 6 and 7 times as potent a corticosteroid as prednisone. In late September, 2022 and early October, 2022 TCC dispensed an additional 8,400 mg of prednisone to SW. During this same period, on September 27, 2022 TCC dispensed 100 tablets of dexamethasone 4mg with instructions to take up to 10 tablets per day. On October 5, 2022 TCC dispensed an additional 200 dexamethasone 4mg tablets with instructions to take up to 20 tablets per day, a dose that would be equivalent to approximately 480 mg of prednisone.

To help put the prior two paragraphs into perspective, the generally accepted starting dosage range of prednisone is between 5mg and 60 mg per day, with a slow tapering of the dose as soon as possible. Doses of the magnitude dispensed by TCC would generally never be seen in a retail pharmacy because it is simply not safe for patients outside of a hospital setting to be consuming hundreds of milligrams of prednisone per day for any length of time. In reviewing the deposition transcripts of the two pharmacists at TCC involved in filling these prescriptions, it appears that neither pharmacist requested or required some clinical documentation of the patient's diagnosis of a very rare disease. One of the pharmacists (Bryk) had no memory of speaking to the prescribing doctor about this patient, and the other pharmacist (Young) testified to a vague memory of such a conversation, but admitted there was no discussion of negative side effects, although there does not appear to be any documentation of even this conversation. The pharmacists did not seem to recognize or acknowledge that corticosteroids in such massive doses are extremely dangerous, nor is there any documentation that they even investigated whether such doses were ever appropriate outside a hospital setting. All competent pharmacists know that corticosteroids are a class of drugs that have multiple serious side effects, and that excessive doses or duration of therapy should be avoided unless absolutely necessary. By accepting the doctor's apparent belief that there is no upper limit on steroid dosing, the pharmacists at TCC failed to exercise their professional judgement, failed to investigate whether such doses were ever acceptable in a retail pharmacy setting, and failed to protect their patient from the foreseeable harm that such doses could cause.



During my 40 years of teaching pharmacy students about their legal and professional obligations, I have always stressed that they have a professional duty to use their knowledge and training when dispensing prescriptions, and it is my experience that these same duties are taught in every accredited pharmacy school. They are taught that they should not blindly follow the instructions of prescribers, but rather they should use their independent professional judgement when evaluating whether to fill or not fill a given prescription. I have cited in classes and continuing education lectures the Pennsylvania case of *Riff v Morgan Pharmacy* that demonstrates that the courts have also adopted this reasoning when looking at the duties of a pharmacist. There is no support in the professional literature or binding Pennsylvania case law that would contradict this duty. Pharmacy is a highly regulated profession that requires a pharmacist to follow both laws and regulations that have been adopted to protect patients from harm. In this case it appears that the pharmacists at TCC failed to question the appropriateness of Dr. Lindner's therapy, failed to evaluate the harm that might be caused by these extremely high doses of corticosteroids, and the result was serious harm to SW.

Should you have any additional questions, please feel free to contact me.

Sincerely yours,

A handwritten signature in blue ink, appearing to read 'Carl Gainor', with a stylized, cursive script.

Carl Gainor, Ph.D., J.D.

**CURRICULUM VITAE**

CARL GAINOR, Ph.D., J.D.

6907 SE 12<sup>th</sup> Circle  
Ocala, Florida 34480-6656

Telephone: (352) 207-4800

**EDUCATION:**

|           |                                                     |
|-----------|-----------------------------------------------------|
| 1961-1963 | University of Michigan                              |
| 1963-1966 | University of Pittsburgh School of Pharmacy<br>B.S. |
| 1967-1968 | M.S.                                                |
| 1968-1972 | Ph.D.                                               |
| 1972-1975 | University of Pittsburgh School of Law<br>J.D.      |

**POSITIONS HELD:**

|           |                                                                 |
|-----------|-----------------------------------------------------------------|
| 1977-2022 | Assistant Professor, University of Pittsburgh                   |
| 1978-2001 | Continuing Education Lecturer to healthcare providers           |
| 1994-2015 | Adjunct Professor, University of Arizona                        |
| 1999-2017 | Adjunct Professor, West Virginia University                     |
| 2010-2019 | Adjunct Professor, Notre Dame of Maryland University            |
| 2012-2020 | Adjunct Professor, Belmont University                           |
| 1978-2003 | Legal Counsel to the Pennsylvania Pharmacists Association       |
| 1976-1992 | Private law practice-Pittsburgh, Pennsylvania                   |
| 1970-1976 | Staff Pharmacist-Montefiore Hospital, Pittsburgh, Pennsylvania  |
| 1966-1967 | Resident in Hospital Pharmacy, Veterans Administration Hospital |

**LICENSURE:**

|      |                                                                                                                                                                         |
|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1966 | Licensed to practice pharmacy in Pennsylvania                                                                                                                           |
| 1969 | Licensed to practice pharmacy in Michigan                                                                                                                               |
| 1975 | Licensed to practice pharmacy in Nevada<br>Admitted to practice Law in the Supreme Court of Pennsylvania<br>Admitted to practice Law in the U.S. Federal District Court |
| 1979 | Admitted to practice before the U.S. Supreme Court                                                                                                                      |
| 2004 | Licensed to practice pharmacy in North Carolina                                                                                                                         |